University of Liverpool
Clinical Trial Training for Investigators

Location: Guild of Students Library Room, University of Liverpool
Course dates: 18th - 22nd September 2023
Course fee: £475, includes course materials, lunch and refreshments
CPD accredited: 30 points awarded for full week attendance
Individual day attendance available: Charged at £95 per day

Faculty includes experts in:
Clinical trials: Professor Paula Williamson, Dr Susanna Dodd
Statistics: Dr Richard Jackson, Dr Girvan Burnside, Professor Jamie Kirkham, Professor James Wason
Qualitative and recruitment research: Professor Peter Bower, Dr Kerry Woolfall, Dr Nicola Harman
Health economics: Professor Dyfrig Hughes

Overview
The number of clinical trials being conducted has increased, and the need for greater efficiency in design, conduct, analysis and reporting has been recognised in both the public and industry sector. The programme will include:
• Trial design
• Trial conduct
• Recruitment of trial participants
• Public and patient involvement
• Analysis and reporting
• Health Informatics
• Health economics

Prerequisites
Understanding of basic statistical concepts is assumed.

Target audience
This course is aimed at health and research professionals, particularly those aiming to become Chief Investigators.

Feedback from previous course
“Speakers all knowledgeable / credible / approachable. Pitched at the right level.”
“The team is clearly very keen and worked hard to make the course happen.”
“The sessions on design and analysis were excellent and were very practical too.”
“The facilitators were excellent and to the point. The practical sessions made the lectures vivid.”
“Comprehensive overview, provided a basic understanding of most key issues I wanted to know about and many I hadn’t considered.”
<table>
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<th>Day</th>
<th>AM SESSION 9.30-12.30</th>
<th>PM SESSION 1.30-4.30</th>
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| Monday 18th | **What do you need to do to design a trial?**  
*Professor Paula Williamson, University of Liverpool*  
Topics: Identifying, defining and justifying the question; the importance of the protocol |
|             | **General design issues**  
*Dr Susanna Dodd, University of Liverpool*  
Topics: Feasibility, external and internal pilot studies; pragmatic and explanatory designs, internal and external validity; sample size considerations |
| Tuesday 19th| **Introduction to different designs**  
*Dr Girvan Burnside, University of Liverpool*  
*Professor James Wason, Newcastle University*  
Topics: Adaptive designs; trials of complex interventions; stepped wedge and cluster randomised trials |
|             | **Recruitment of trial participants**  
*Dr Kerry Woolfall, University of Liverpool*  
*Dr Nicola Harman, University of Liverpool*  
Topics: Barriers and facilitators; effective recruitment and retention strategies; recruitment monitoring |
| Wednesday 20th | **Trial conduct (part 1)**  
*Dr Emma Bedson, Liverpool Clinical Trials Centre*  
*Mrs Tracy Moitt, Liverpool Clinical Trials Centre*  
*Ms Claire Johnson, Liverpool Clinical Trials Centre*  
*Mrs Sharon Kean, Liverpool Clinical Trials Centre*  
Topics: Ethical, legal and regulatory requirements; pharmacovigilance; barriers and facilitators to setting up sites; data sources; information systems and data management |
|             | **Virtual visit to the Liverpool Clinical Trials Centre** |
| Thursday 21st | **Public and Patient Involvement**  
*Professor Peter Bower, University of Manchester*  
*Dr Claire Planner, University of Manchester*  
Topics: Basic principles of patient centred trials; evidence of benefit |
|             | **Keynote talk ‘How to be a good Chief Investigator’**  
*Professor Tony Marson*  
**Trial conduct (part 2)**  
*Professor Carrol Gamble, University of Liverpool*  
Topics: Risk assessment; risk-based monitoring and safety monitoring; trial oversight committees |
| Friday 22nd | **Analysis and reporting (part 1)**  
*Dr Richard Jackson, University of Liverpool*  
Topics: Key principles of trial analysis; intention to treat analysis; causal analysis |
|             | **Analysis and reporting (part 2)**  
*Professor Dyfrig Hughes, Bangor University*  
*Professor Jamie Kirkham, University of Manchester*  
Topics: Basic principles of health economics; methods of economic evaluation; economic outcomes; good practice in trial reporting |
|             | **Registration and coffee**  
**Welcome, introductions and overview of course** |